REMARKS

This amendment is submitted in response to the final Office Action mailed on December 17, 2004. Claims 6 and 23-24 are pending in this application. Claims 1-5 and 7-21 have been withdrawn previously. Claim 22 has been canceled previously. In the Office Action, Claims 6 and 23-24 are rejected under 35 U.S.C. §112, first and second paragraphs. In response Claim 6 has been amended. This amendment does not add new matter. In view of the amendment and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 6 and 23-24 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action alleges that the claim term "increasing insulin sensitivity" is indefinite.

Applicants respectfully disagree with the Patent Office's assertion regarding the claim term "increasing insulin sensitivity." Applicants respectfully submit that the Patent Office's focus during examination of claims for compliance with the definiteness requirement of 35 U.S.C. §112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. MPEP 2173.02. For example, Claim 6 recites a method for increasing insulin sensitivity in a mammal comprising the step of orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day. Although the preamble of Claim 6 recites the term "increasing insulin sensitivity," the body of the Claim 6 recites orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day. Thus, the body of Claim 6 clearly defines the metes and bounds of the claimed subject matter. As a result, upon reviewing the claim in its entirety, one of ordinary skill in the art would clearly be apprised of the scope of the claimed subject matter. MPEP 2173.02.

In addition, the specification, for example, provides on page 1 at lines 21-25 that propionate, a short chain fatty acid, increases insulin sensitivity in addition to other physiologic parameters. This beneficial effect may be important/relevant in the nutritional management of

conditions, such as diabetes, hypercholesterolemia and/or the like as disclosed in the specification on page 4 at lines 31-32. As the skilled artisan should understand, insulin sensitivity is reduced as insulin resistance modulates triglyceride metabolism, that is, activates triglyceride-lipase activity freeing free fatty acids from the pool which again enhance insulin resistance.

Based on at least these noted reasons, Applicants believe that Claim 6 and Claims 23-24 that depend from Claim 6 fully comply with 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 6 and 23-24 under 35 U.S.C. §112, second paragraph, be withdrawn.

Based on at least these noted reasons, Applicants believe that Claim 6 and Claims 23-24 that depend from Claim 6 fully comply with 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 6 and 23-24 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 6 and 23-24 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 6 and 23-24 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Applicants have amended Claim 6 to include, in part, the step of orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000. Contrary to the Patent Office's assertion, Applicants respectfully submit that the limitation "having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day" is fully supported by the as-filed specification. As discussed in the previous response, support for this limitation is found, for example, in the specification at page 5, lines 4-5. Further, the Patent Office admits the oral administration of dextran. See, Office Action, pages 3 and 5. The dextran of the claimed invention is a high molecular weight dextran, such as above about 500,000. See, specification, page 3, lines 11-13. The amount of dextran that the patient (e.g. mammal) receives as part of a nutritional composition is preferably in the range of about 2 g to about 15 g per day as explicitly disclosed in the specification, at page 5, lines 4-5.

The specification also explicitly discloses administering dextran to a mammal, which increases the production of propionate in the gastro-intestinal tract. See, Specification, Examples 1-3. In turn, proprionate is known to increase insulin sensitivity in a mammal as disclosed in the specification at page 1 (citing *Roberfroid et al*; 1998; *Annu. Rev. Nutr.*; 18:117-43, which is incorporated into the specification by reference). Further, because insulin sensitivity is a measure for the effectiveness of removing glucose from the blood stream, Applicants respectfully submit that propionate as detailed on page 1 at lines 21-25 of the present application enhances glycolysis and inhibits gluconeogenesis, both clear indicators of low blood glucose levels, thus again demonstrating the impact of propionate on glucose metabolism. As insulin is the only known molecule lowering blood glucose elevation, propionate may indirectly trigger a more effective way of absorbing glucose from the blood, and thus enhancing/increasing insulin sensitivity, which in turn may reasonably be understood as having an effect of lowering glucose levels of the blood. Moreover, propionate appears to mediate normalization of the blood glucose level in mammals. Accordingly, in view of these disclosures, one having ordinary skill in the art would understand that the limitation "having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day" for the purpose of increasing insulin sensitivity is fully supported by the as-filed specification.

Regarding the enablement requirement, Applicants respectfully submit that one having ordinary skill in the art would be able to make/use the claimed invention based on Applicants' specification. As discussed previously, the written description and examples disclosed in the specification provide adequate support and guidance to one of ordinary skill in the art on how to make and use the claimed invention for orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day.

The present invention is based on the discovery that fermentation of dextran by micro-organisms in the gastro-intestinal tract results in the production of relatively higher amounts of propionate as compared to other non-digestible polysaccharides. Thus, as propionate is a physiologic modulator of fat and glucose metabolism, dextran modulates blood sugar and lipids. Therefore, the oral administration of dextran provides a convenient and simple way of selectively increasing the production of propionate in the gastro-intestinal tract and beneficially modulates

physiologic parameters. Accordingly, oral administration of dextran provides a method for increasing insulin sensitivity.

In turn, Applicants respectfully submit that one having ordinary skill in the art would easily be capable of performing this process without undue experimentation. The claims are essentially directed, in part, to the method of orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 wherein dextran is administered in an amount from about 2g per day to about 15g per day. Methods of orally administering compositions to persons are well known in the art. The specification sufficiently discloses nutritional compositions having dextran having a molecular weight above about 500,000. Indeed, the claimed method is easy to practice. It is noted that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example of administering the composition to the patient is disclosed. MPEP 2164.02.

However, Applicants provide sufficient working examples of the claimed invention. For example, Example 3 provides the consumption (i.e. oral administration) of an acute dose of 15 grams Dextran T2000 and a chronic dose of 10g Dextran T2000 per day as disclosed in the specification on page 8 at lines 13-16. Further, Dextran T2000 is generally recognized in the art as dextran having a molecular weight of 2,000,000 where T2000 is generally recognized as an abbreviation of the molecular weight mass by the thousandth part. Therefore, Applicants believe that the claimed invention is clearly enabled as supported by the specification.

Based on at least these noted reasons, Applicants believe that 6 and 23-24 fully comply with 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the rejections of 6 and 23-24 under 35 U.S.C. §112, first paragraph, be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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